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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/929,986	08/14/2001	Olivier Civelli	9516	9873

151 7590 10/06/2003
HOFFMANN-LA ROCHE INC.
PATENT LAW DEPARTMENT
340 KINGSLAND STREET
NUTLEY, NJ 07110

EXAMINER

GUCKER, STEPHEN

ART UNIT	PAPER NUMBER
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1647

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DATE MAILED: 10/06/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/929,986

Applicant(s)

Cirelli et al.

Examiner

Stephen Gucker

Group Art Unit

1647

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- ☒ Responsive to communication(s) filed on 1/25/02
- ☐ This action is FINAL.
- ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- ☒ Claim(s) 1-4 is/are pending in the application.
- ☐ Of the above claim(s) is/are withdrawn from consideration.
- ☐ Claim(s) is/are allowed.
- ☒ Claim(s) 1-4 is/are rejected.
- ☐ Claim(s) is/are objected to.
- ☐ Claim(s) are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
 - ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been received.
 - ☐ received in Application No. (Series Code/Serial Number) _____
 - ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

Attachment(s)

- ☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 4
- ☐ Interview Summary, PTO-413
- ☒ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Other _____

Office Action Summary

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DETAILED ACTION

1. Acknowledgment is made of applicant's claim for foreign priority based on an application filed in Europe on 6/13/96. It is noted, however, that applicant has not filed a certified copy of the foreign application as required by 35 U.S.C. 119(b).

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1-4 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for Orphanin FQ (SEQ ID NO:1), does not reasonably provide enablement for pharmacologically active derivatives thereof. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. According to the specification, derivatives of Orphanin FQ (SEQ ID NO:1) include peptides where amino acids are substituted for other amino acids. This is not routine experimentation but is in fact painstaking as noted by Rudinger (see page 6). The specification does not provide an adequate written description, guidance, or any working examples to teach the artisan which amino acids are critical to the biological function of Orphanin FQ (SEQ ID NO:1) and which are not. The specification does not teach which amino acids in Orphanin FQ (SEQ ID NO:1) may be substituted, nor does the specification teach which amino acids can be appropriately selected as substitutes for the amino

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acids shown as SEQ ID NO:1. The peptide art is unpredictable (again, consult Rudinger), and biological function cannot be reliably determined by chemical structure or amino acid sequence. Neither can the structure or sequence of a peptide be reliably determined based on its biological function. Because the unpredictability in the art is high, the scope of the claims must be limited to what the disclosure can reasonably support, particularly when the specification fails to teach, at the very minimum, any biologically active fragments, derivatives, or successfully substituted amino acids in the sequence comprising Orphanin FQ (SEQ ID NO:1).

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

5. Claims 1 and 4 are rejected under 35 U.S.C. 102(e) as being anticipated by US 5,821,219 ('219). The '219 patent teaches the Orphanin FQ (SEQ ID NO:1) pharmaceutical composition

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(column 4, lines 1-10, column 17, lines 27-53, and column 23, lines 55-66) and therapeutic methods of use in psychiatric or neurological disorders (column 31, line 53 to column 32, line 42).

6. Claims 1 and 4 are rejected under 35 U.S.C. 102(e) as being anticipated by US 5,837,809 ('809). The '809 patent teaches the Orphanin FQ (SEQ ID NO:1) pharmaceutical composition and therapeutic methods of use in psychiatric or neurological disorders (column 4, lines 10-40, column 12, lines 31-56, and column 20, lines 19-65).

7. Claims 2-3 may be allowable if they are amended to obviate the enablement rejection and include all the limitations presently in the claims and the base claim to avoid the prior art rejection.

8. As allowable subject matter has been indicated, applicant's reply must either comply with all formal requirements or specifically traverse each requirement not complied with. See 37 CFR 1.111(b) and MPEP § 707.07(a).

9. No claim is allowed.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen Gucker whose telephone number is (703) 308-6571. The examiner can normally be reached on Monday to Friday from 0930 to 1800. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623. The fax phone number for this Group is currently (703) 308-4242, but Applicant should confirm this by phoning the Examiner before faxing.

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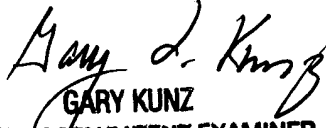
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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

S6

Stephen Gucker

October 1, 2003


GARY KUNZ
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600